



PATENT  
MSB-7213

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: PETRA BOYLE )  
                  GAYLE D. WETZEL ) DECLARATION UNDER  
                  KENNETH J. LEMBACH )  
  ) 37 C.F.R. § 1.132  
Serial No.: 08/026,957 )  
  ) EXAMINER: R. D. BUDENS  
Filed: March 5, 1993 )  
  ) ART UNIT: 1806  
For: HUMAN ANTI-TNF ANTIBODIES )

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

I, Matthias Wabl, declare as follows:

1. I have been awarded a Ph.D. degree in Biology from the Max Planck Institute, Berlin and have approximately 16 years experience in making cell lines that express monoclonal antibodies.

2. UTILITY: The above-entitled Patent Application is concerned with human monoclonal antibodies that specifically bind to TNF $\alpha$ . I understand the Examiner has rejected the claims in that Patent Application on the ground that Applicants have not mentioned specific uses for the antibodies. In my opinion, a variety of specific uses would immediately be obvious to a person skilled in the art. For example, it is well known that any monoclonal antibody, once generated, can be used in a variety of immunoassays which would be inherently useful for not only research but as diagnostic tools. As shown in the enclosed catalog copies, anti-TNF antibodies are commercially available, thus confirming their obvious utility.

In addition, I am aware of clinical studies currently in progress using murine monoclonal antibodies that bind to TNF $\alpha$ . See the

attached copy of a Poster Session No. 696, presented at the 3rd ICAAC meeting, October 17, 1993. See also the enclosed copy of an article that appeared in the July 15, 1994, Genetic Engineering News showing that Chiron/Miles is developing an anti-TNF monoclonal antibody for the targeting of TNF $\alpha$ .

3. ENABLEMENT: I understand the Examiner states it is not clear from the teachings of the Patent Application that one of ordinary skill in the art could make other human anti-TNF $\alpha$  monoclonal antibodies that bind specifically to TNF $\alpha$  without undue experimentation. I have reviewed the work leading to the Applicants' patent claims and believe that one skilled in the art, given the disclosure of the Patent Application and a related publication, Cellular Immunology, 152, 569-581 (1993), copy enclosed, could duplicate the Applicants' work and generate other cell lines that express human monoclonal antibodies that bind specifically to TNF $\alpha$  without undue experimentation using known screening techniques.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardizethe validity of the Application or any patents issuing thereon.

July 28, 94  
Date

Matthias Wabl  
Matthias Wabl, Ph.D.